K092428

510(k) Summary

BIO-OSS COLLAGEN®

1. SPONSOR

MAR 1 8 2010

Ed. Geistlich Soehne Ag für Chemische Industrie
Geistlich Pharma Ag
Bahnhofstrasse 40
CH-6110 Wolhusen
SWITZERLAND

Contact Person: Peter S. Reichertz, (202) 772-5333, preichertz@sheppardmullin.com
Date Prepared: March 12, 2010

2. DEVICE NAME

Proprietary Name	BIO-OSS COLLAGEN®
Common/Usual Name:	Natural Bone Grafting Material Plus Collagen
Classification Name:	Bone grafting material, animal source (NPM)

3. PREDICATE DEVICES

BIO-OSS COLLAGEN® (K03-3815 and K97-4399), 21 C.F.R. § 872.3930

4. INTENDED USE

Augmentation or reconstructive treatment of alveolar ridge
Filling of periodontal defects
Filling of defects after root resection, apicoectomy, and cystectomy
Filling of extraction sockets to enhance preservation of the alveolar ridge
Elevation of maxillary sinus floor
Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

5. DEVICE DESCRIPTION

BIO-OSS COLLAGEN® is a combination of purified cancellous natural bone mineral granules and 10% collagen fibers in a block form and is sterilized by γ-irradiation.

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6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The only change is in one step of the alkalinization process of the previously cleared product. The change involved is a reduction in the amount by molar concentration of the alkaline treatment coupled with a change in a length (in hours) of the compounding alkalization step. No other modification or technical changes were made. The rest of the manufacturing process is identical to that reviewed in prior 510(k) notifications for this product (K974399 and K033815). Importantly, the principal virus inactivation step does not change.

To substantiate that the change in the alkalinization step does not affect the safety or efficacy of the product, the Company commissioned an evaluation of the revised manufacturing process on the viral safety level in the collagen MGR portion of the product and revalidated the manufacturing process using the slightly revised alkalinization step.

The revised alkaline treatment was found to be efficient in inactivating the three viruses tested – Pseudorabies Virus (PRV), Reovirus type 3 (Reo 3) and Porcine Parovirus (PPV). Viral inactivation was found to clear the product of PRV and PPV, and viral inactivation and removal (by rinsing) of physical viral particles were shown to clear the product of Reo 3. (The acidic treatment was similarly found to be efficient at clearing the three viruses).

Using collagen MGR prepared with the revised alkalinization step, four lots of product were manufactured and tested for compliance with the final release specifications for the product. All tests were found to be within limits and the revised process, hence, the change in the alkalinization step did not affect the safety, efficacy or quality of the product.

As the alkalinization step has been validated to demonstrate adequate viral inactivation (and clearance), and the quality of the product has not otherwise changed, the BIO-OSS COLLAGEN® product manufactured in accordance with the revised alkalinization step is substantially equivalent to the previously cleared product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 18 2010

Ed. Geistlich Soehne Ag Für Chemische Industrie
C/O Mr. Peter S. Reichertz
Official Correspondent
Sheppard Mullin Richter & Hampton LLP
1300 I Street, N.W., 11th Floor East
Washington, DC 20005

Re: K092428
Trade/Device Name: BIO-OSS COLLAGEN®
Regulation Number: 21CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: March 12, 2010
Received: March 15, 2010

Dear Mr. Reichertz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092428

Device Name: BIO-OSS COLLAGEN®

Indications for Use: Augmentation or reconstructive treatment of alveolar ridge
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Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Part 21 CFR 801 Subpart D) OR Over-the-Counter Use ___ (21 CFR 801 Subpart C)

R Bodz DDS for Dr. K.P. Mulay

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: ~~R Bodz D~~ K092428